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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,504	07/25/2003	Clark C. Davis	1001.1869101	1503

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
06/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/604,504	DAVIS ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *88-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *88-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/24/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 24, 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 88-97, 99, 100 and 102-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) in view of Shiber (5,135,531), as evidenced by Hernandez et al (5,396,212).

Jacobsen et al disclose a coronary guidewire system and further disclose an elongate core wire (501) having a distal portion; a metallic tubular member (514) disposed over the distal portion, the tubular member having a proximal end and a distal end; the tubular member (514) has a plurality of slots defined therein (see Figure 18); a coil (538) disposed between the core wire (501) and the tubular member (514), the coil having a distal end disposed adjacent the distal end of the tubular member and a

proximal end disposed distally of the proximal end of the tubular member (514); the core wire (501) includes stainless steel (see Column 10, lines 9-10); the tubular member (514) includes nickel-titanium alloy or a superelastic nickel-titanium alloy (see Column 10, lines 19-22); the coil (538) includes radiopaque material (see Column 11, lines 66-67 and Column 12, lines 1-5); the coil is attached to the core wire (501), the tubular member (514) or both with an adhesive at the proximal end of the coil (538) (the coil (538) is attached to the core (501) via medial coil (532), which coincides with the adhesive joint at (516)); the coil (538) is attached to the core wire (501), the tubular member (514) or both with an adhesive at the distal end of the coil (538) (at 518 in Figure 18); and the coil (538) is configured to increase the radiopacity of the guidewire (see Column 11, lines 66-67 and Column 12, lines 1-5).

Jacobsen et al however does not disclose an edge wound coil; the edge wound coil is configured to have a minimal impact on the flexibility of the wire; and the edge wound coil is configured to improve torsional stiffness, torsional strength or both of the guidewire.

Shiber, as evidenced by Hernandez et al, discloses a guided atherectomy means and further discloses an edge wound coil; the edge wound coil is configured to have a minimal impact on the flexibility of the wire (the device is capable of navigating the vasculature of a patient, see Figure 1); and the edge wound coil is configured to improve torsional stiffness, torsional strength or both of the wire (the edge wound coil allows the coil to turn, therefore the coil would provide torsional strength). See Figure 11; and Column 6, lines 45-56.

One of ordinary skill in the art would recognize Shiber implicitly teaches a coil that is created from a trapezoidal cross-sectioned wire and when the coil is formed, the trapezoidal shape becomes a rectangular cross section. In order to obtain the rectangular cross section as taught by Shiber, the wire would have to initially be of a trapezoidal shape before being formed into the coil, because if the wire was initially of a rectangular cross section, the formed coil would be formed into a trapezoidal cross section due to the increase of material on the inside of the formed coil. Hernandez et al discloses a means for winding transformer wire and further discloses the fact that a wire having a rectangular cross-section prior to bending about a radius would become a wire with a trapezoidal cross-section after bending about a radius. See Column 2, lines 53-63 of Hernandez et al. Therefore, Shiber implicitly discloses the use of a trapezoidal shaped flat stock prior to winding into a coil to form the shown rectangular cross-section.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guidewire coil of Jacobsen et al to include the use of a non-circular cross section, as per the teachings of Shiber, since the substitution of a non-circular cross-section coil in the place of a circular cross-section coil would provide the predictable result of being able to navigate a guidewire through the vasculature of the patient.

4. Claims 98, 101 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) in view of Shiber (5,135,531), as

evidenced by Hernandez et al (5,396,212) as applied to claims 88, 99 and 102 above, and further in view of Kolehmainen et al (5,997,487).

Jacobsen et al and Shiber, as evidenced by Hernandez et al, as discussed above, disclose a guidewire with an edge wound distal coil but do not disclose a space is defined within the tubular member between the proximal end of the coil and the proximal end of the tubular member, and wherein the space is substantially free of any other structures of the guidewire.

Kolehmainen et al disclose an infusion wire and further disclose a space is defined within the tubular member (50) between the proximal end of the coil (40) and the proximal end of the tubular member, and wherein the space is substantially free of any other structures of the guidewire. See Figures 4 and 6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Jacobsen et al and Shiber as evidenced by Hernandez et al, to include a space between the proximal end of the coil and the proximal end of the tubular member, as per the teachings of Kolehmainen et al, since it would provide an alternate means of increased flexibility at the distal end of the guidewire, while providing a means of visualizing the distal end of the wire within the body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736